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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,196	01/24/2002	Y. Tom Tang	PF-0561 USN	3875

7590 03/23/2005

Legal Department
Incyte Genomics Inc
3160 Porter Drive
Palo Alto, CA 94304

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,196	TANG ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HR

DETAILED ACTION

1. Applicant's response and amendment filed January 6, 2005 is acknowledged and entered. Claims 3-11 are pending and under examination.

2. The rejection of claim 11 under 35 U.S.C. 101 for being directed to non-statutory subject matter is withdrawn in view of Applicant's amendment to "An isolated host cell".

Response to Arguments

3. The rejection of claims 3-11 under 35 U.S.C. 101 for not being supported by either a specific, substantial and credible asserted utility, or a well established utility, is maintained for reasons of record. Applicant's arguments filed January 6, 2005 have been considered carefully but fail to persuade. Applicant's substantive arguments are primarily drawn to the following:

- Applicant argues that the utility requirement for the claims has been met because expression of MACP-2 is correlated with proliferative diseases, in particular prostate cancer. Applicant points to Tables 1, 3 and 4 that demonstrate that MACP-2 is associated with prostate cancer, and that MACP-2 nucleotide is found in 71.4% of cDNA libraries that are proliferative in nature.
    - In response, the Office has considered the data presented in Tables 1, 3 and 4 of the specification. However, these data do not demonstrate that MACP-2 is indicative of prostate cancer or any other proliferative disease. The data show that the MACP-2 nucleotide is present in certain libraries, but Applicant has not provided evidence that detection of MACP-2 in prostate cancer patients is any different from detection of MACP-2 in healthy individuals. According to one of

skill in the art, the presence of MACP-2 in a library derived from a prostate cancer patient fails to directly translate to diagnosis without further testing.

- Applicant argues that one of skill in the art would recognize the link between MACP-2 and cell proliferative disease, particularly prostate cancer. In view of data, MACP-2 is useful for diagnosing disease.
    - In response, lacking a connection between MACP-2 and proliferative disease and prostate cancer, one of skill in the art would not recognize how MACP-2 is useful. The instant claims are drawn to polynucleotides that encode a protein of as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as MACP-2, or of nucleic acids encoding such or fragments thereof, the instant invention is incomplete. In the absence of any functional or biological significance of this protein, there is no immediately obvious patentable use for it.

4. Claims 3-11 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility, or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. For reasons of record, claims 4 and 8 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's arguments have been

carefully considered but fail to persuade. Applicant's substantive arguments are primarily drawn to the following:

- Applicant argues that the polypeptides that share 90% sequence identity to SEQ ID NO: 2 are adequately described in view of Table 2, page 51 of the specification. The Table shows potential glycosylation sites, signature sequences, and potential phosphorylation sites. The same argument is made for polynucleotides that are 90% sequence identical to SEQ ID NO: 7.
    - In response, the Office has considered the information provided in Table 2 regarding SEQ ID NO: 2. Even though Applicant argues that 90% sequence identity allows 38 amino acid changes, one of skill in the art would not know what variants of 90% are acceptable. One would not know which variants are acceptable because the disclosure fails to provide a detailed description directed to the intended variants of the polypeptide of SEQ ID NO: 2, or the polynucleotide of SEQ ID NO: 7, including critical features of such that should be conserved. It is not sufficient to name the claimed variant nucleic acids that can encode for polypeptides comprising 90% identity to SEQ ID NO: 2, or the variant polypeptides without disclosure of what features define the claimed genus. The disclosure fails to describe the common attributes or characteristics that identify the members of the genus.
- Applicant points to *In re Wallach*, 2002 Pat. App. LEXIS 327 (BPAI, 2002), in which the Board held that a polypeptide sequence alone puts one in possession of all of the entire

genus of polynucleotide variants that could possibly encode that polypeptide. Applicant also argues that amino acid and nucleic acid code degenerates are adequately described.

- In response, the Office has reviewed *In re Wallach*, 71 USPQ2nd 1939 (CA FC 2004). Upon review, the circumstances of the instant claims and those in *In re Wallach* differ. In the instant case, the sequences of the protein and the DNA have been provided. In the other case, only a partial protein sequence was provided, and no DNA sequence was provided. Given these circumstances, comparison of the two cases is not proper with regard to Applicant's conclusion which is out of context.
- Regardless, the Office agrees that description of a representative number of species is sufficient to meet the written description requirement, however, Applicant has not done this. Applicant has only provided one amino acid sequence, and one DNA sequence. This disclosure is not supportive of claims to sequences that are 90% sequence identical. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a partial structure in the form of a recitation of percent identity. The specification does not identify any particular portion of the structure that must be conserved,

nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. The only adequately described species is a polypeptide comprising SEQ ID NO: 2, and a polynucleotide comprising SEQ ID NO: 7. No active variants are disclosed. Accordingly, the specification does not provide adequate written description of the claimed genus.

6. For reasons of record, claim 5 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's arguments have been carefully considered, but fail to persuade. Applicant mainly argues that the specification (page 16) defines this the term, "stringent conditions". The Office has reviewed the specification on page 16, but finds that the definition is exemplative, but not definitional. Applicant only provides an example of stringent conditions, which does not suffice for what stringent conditions actually are. The use of the term "stringent conditions" is unclear because it is a relative term, subject to individual interpretation. The exact conditions are not disclosed which qualify the conditions as stringent.

Conclusion

7. No claim is allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

JAMES HOUSEL 3/21/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

SBC

Stacy B. Chen
March 10, 2005